



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,617	09/09/2003	Lloyd G. Mitchell	AP35003-A	2539
38485	7590	04/12/2006	EXAMINER	
ARENT FOX PLLC 1675 BROADWAY NEW YORK, NY 10019			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 04/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,617	Applicant(s) MITCHELL ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 13-18 and 27 is/are allowed.
- 6) ☒ Claim(s) 9-12 and 19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Objections to the Specification

The amendment filed 10/7/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants incorporate by reference the disclosures of the 10/374,784 and 60/359,948 applications. The incorporation by reference statement adds new matter because as noted in MPEP 601:

For the incorporation by reference to be effective as a proper safeguard, the incorporation by reference statement must be filed at the time of filing of the later-filed application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)).

It is noted that the Transmittal papers contain an incorporation by reference statement concerning the 10/374,784 application. However, the incorporation statement indicates that "incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts" and hence said incorporation statement is not as broad as the language filed in the amendment of 10/7/05

Applicant is required to cancel the new matter in the reply to this Office Action.

Priority

With regard to priority of the claimed subject matter, claims 1-27 are granted priority to the filing date of the instant application (9/9/03) as no parent application teaches activation of a photosensitizer by a light producing protein or enzyme. Also

Art Unit: 1636

priority is granted back to the instant filing date because the instant application is the first to recite cells, nucleic acid constructs, conditionally replicative adenoviruses and methods of producing chimeric mRNAs involving "light producing" or "light inducing" protein or enzyme. The parent applications only recite a protein or enzyme which provides a fluorescent or bioluminescent signal. Light producing or inducing proteins or enzymes are broader than molecules which provide a fluorescent or bioluminescent signal. For example, light producing proteins or enzymes include phosphorescent proteins. Therefore, the scope of the instant claims is broader than what was provided in the parent applications and said applications cannot provide support for the instantly claimed limitations.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1636

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-48, 54, 62-64, 92 of copending Application No. 10/434,727 (hereafter the '727 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action and for reasons outlined below.

Applicants have responded to this rejection by amending claims 19, 21, 23 and 25 to delete recitation of an adenoviral polypeptide to be trans-spliced. Applicants assert that since the instant claims are limited to a sequence encoding a light producing protein or enzyme and the claims of the '727 application only recite adenoviral proteins, the rejection should be withdrawn.

Applicant's arguments filed 10/7/05 have been fully considered but they are not persuasive. Claims 54 and 92 of the '727 application recite that the nucleotide sequence to be trans-spliced includes a sequence encoding a bioluminescent or chemiluminescent polypeptide. Therefore, since the claims in the '727 application recite the same limitations as currently claimed, i.e. recite recombinant conditionally replicative adenoviruses comprising a 3' splice region comprising a 3' splice acceptor site, a spacer region that separates the 3' splice region from the target binding domain, etc., and recite that the sequence to be trans-spliced can include a sequence encoding a

Art Unit: 1636

light producing polypeptide such as a bioluminescent or chemiluminescent polypeptide, it must be considered that the instant claims are obvious over the '727 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 19-26 are directed to an invention not patentably distinct from claims 46-48, 54, 62-64, 92 of commonly assigned 10/434,727. Specifically, the claims are not patentably distinct for the reasons outlined above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/434,727, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Art Unit: 1636

Applicants have responded to this requirement by indicating that the claimed subject matter is entitled to priority back to the 60/359,948 application. However, priority is granted back to the instant filing date for reasons cited above (See Priority section on pp. 2-3 of this Office Action). The above requirement is therefore maintained.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell et al. (US 2004/0058344, Serial Number 10/374,784).

The applied reference has a common inventor (and Assignee) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants responded to this rejection by amending claims 9 and 11 to recite a nucleic acid molecule comprising a sequence encoding a light producing protein or enzyme wherein said light producing protein or enzyme activates a cytotoxic photosensitizer which causes cell death. Applicants also argue that support for the claimed subject matter should be granted back to the 60/359,948 application and hence the Mitchell et al. publication is not prior art.

Applicants' arguments have been considered but are not persuasive. Priority for the claimed invention is granted back to the filing date of the instant application for reasons outlined above. With regard to the nucleic acid claims 9-12, the limitation that the light generated by the light producing protein or enzyme subsequently activates a photosensitizer does not limit the nature or structure of the nucleic acid. The claims read on a nucleic acid with certain structural features, one of these features is a nucleotide sequence encoding a light producing protein or enzyme. The Mitchell et al. publication teaches nucleic acids with the same characteristics wherein the light producing protein or enzyme can be a bioluminescent or fluorescent molecule (See for example [0053]). The instant application teaches that bioluminescent or fluorescent molecules can be used to provide light to activate photosensitizers to kill target cells. Therefore, Mitchell et al. anticipates the claimed invention.

Claims 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Otto (US 2004/0038403, Serial Number 10/434/727).

The applied reference has a common inventor (and Assignee) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection is maintained for reasons of record and for reasons outlined below.

Applicants traversed this rejection by amending the claims to limit them to a light producing protein and argue that the claimed invention is entitled to priority to the 60/359,948 application.

Applicants' arguments have been considered but are not persuasive. Priority for the claimed invention is granted back to the filing date of the instant application for reasons cited above. The claims are anticipated by the Otto publication because Otto teaches recombinant conditionally replicative adenoviruses with the same characteristics and wherein the sequences to be trans-spliced include genes encoding bioluminescent and fluorescent molecules (See for example, paragraph [0034]).

Any rejections not repeated in this Office Action are withdrawn.

The substitute Drawings filed 10/7/05 are acceptable.

Art Unit: 1636

Claims 1-8, 13-18 and 27 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
March 21, 2006


DAVID GUZO
PRIMARY EXAMINER